REMARKS/ARGUMENTS

The claims are 1-20 and 22-25. Claim 21 has been canceled in favor of new claim 25 to better define the invention. Accordingly, claims 22-24, which previously depended on claim 21 have been amended to depend on new claim 25. These claims and claims 1-20 have also been amended to improve their form or to delete reference numerals. Claim 7 has also been amended to conform with FIGS. 1-5. Reconsideration is expressly requested.

Claim 7 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claim 7 was said not to match with FIGS. 1-5, because claim 7 recites that the main injection device has a channel 8, whereas according to FIGS. 1-5, a channel 8 belongs to the pre-injection device part.

In response, Applicant has amended claim 7 so as to match with FIGS. 1-5, which it is respectfully submitted overcomes the Examiner's rejection under 35 U.S.C. 112, first paragraph.

Claim 13 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because reference numeral 8 is used to denote

both the chamber and the channel. In response, Applicant has, *inter alia*, amended claim 13 to delete such reference numeral thereby obviating the Examiner's rejection under 35 U.S.C. 112, second paragraph.

Claims 1-16 and 19-24 were rejected under 35 U.S.C. 102(b) as being anticipated by *Neracher WO 02/49697*. Claims 1, 13-14, 17-18 were rejected under 35 U.S.C. 102(b) as being anticipated by *Dixon U.S. Patent No. 4,722,728*.

This rejection is respectfully traversed.

As set forth in claim 1 as amended, Applicant's invention provides a device for needle-free injection of a medium into the tissue of a human or an animal. The device includes a needle-free pre-injection device for production of a high-pressure jet of a pre-injection medium for producing an injection channel by means of a high pressure and a small volume, and a main injection device for introduction of the medium to be injected with a great volume and a low pressure in comparison with the volume and pressure of the pre-injection device.

As set forth in claim 4 as amended, Applicant's invention provides a device for needle-free production of an injection channel in the tissue of a human or an animal, for introduction of a medium to be injected into the tissue, wherein a pre-injection device is provided ahead of a main injection device that contains the medium to be injected. A chamber of the pre-injection device provided for accommodation of a pre-injection medium has a nozzle intended to be set onto the skin. The pre-injection device has a pressure-production device for producing a high-pressure jet of the pre-injection medium that exists from the nozzle, and the chamber has a volume sized exclusively for producing the injection channel.

As set forth in new claim 25, Applicant's invention provides a method for needle-free injection of a medium into human or animal tissue in which a device is provided that includes a needle-free pre-injection device for production of a high-pressure jet of a pre-injection medium for producing an injection channel with a high pressure and a small volume and a main injection device for introduction of the medium to be injected with a great volume and a low pressure in comparison with the volume and pressure of the pre-injection device. The high-pressure jet of the pre-injection medium is first produced via

the needle-free pre-injection device, and the injection channel is produced with the high-pressure jet. Subsequently, the medium to be injected into the tissue is introduced through the injection channel.

In this way, Applicant's invention provides a device, which can be used to inject a greater amount, for example, several milliliters into the tissue in a needle-free manner and with which an injection channel can be produced in the tissue in a needless manner for subsequent injection of a medium to be injected. In addition, Applicant's invention provides a method with which several milliliters of a medium can be injected without a needle and without repeated placement against the skin.

Contrary to the Examiner's position, *Neracher* fails to disclose or suggest an injection device for needle-free injection including a pre-injection and a main injection device. The device shown in FIG. 1a of *Neracher* is the propulsion system 1 and the device shown in FIG. 1b of *Neracher* is a disposable capsule 3 which has to be used in combination with the propulsion system 1 and contains the injectable liquid 2. FIGS. 2a and 2b of *Neracher* show an alternative embodiment of the generation of the propulsive force, which is needed to inject the liquid 2 from

the capsule 3. There is no disclosure or suggestion of Applicant's device or method, which uses a two-step injection procedure using a pre- and a main injection device for injecting two different media so that the pre-injection device can be used instead of a needle in combination with, for example, normal syringes.

For example, with Applicant's method as recited in new claim 25, two different volumes of two different media are injected. In contrast, *Neracher* discloses the injection of only one medium. Although *Neracher* also discloses the injection with two different pressures in the second embodiment, in contrast to Applicant's method as recited in new claim 25, *Neracher* injects one medium with two different pressures and cannot use a separate pre-injection medium. In *Neracher's* device, the first and second propulsion force are applied to one volume of an injection medium. In contrast, with Applicant's invention as recited in new claim 25, the pre-injection medium is located in a separated chamber from the main injection medium, which has the great advantage of separating the two mediums so two different media can be used. For example, an anesthetic can be used as a pre-injection medium so that the injection is more comfortable for the patient.

Although *Neracher* discloses an opportunity to inject needlelessly a liquid with two different pressures, it is respectfully submitted that Applicant's two-step injection procedure is quite different from *Neracher* in that a very different propulsion system and a different trigger mechanism are used.

It is respectfully submitted, moreover, that *Neracher* teaches away from Applicant's device and method as recited in claims 1 and 4, and claim 25, respectively, because *Neracher* uses two different injection pressures to control the injection depth. See page 14, lines 21-24 of *Neracher*, and never thought about a really two-step injection system with different injection media. Further, with Applicant's device and method, the pre-injection device can be used in combination with a normal syringe as the main injection device, thereby permitting the pre-injection device to be used instead of a needle and permitting much bigger volumes to be injected compared to the needleless injection devices of the prior art.

Claim 2 more specifically recites a device for needle-free injection of a medium into the tissue of a human or an animal,

wherein the pre-injection device has a first chamber for accommodating a pre-injection medium and the main injection device has a second chamber for accommodating a medium to be injected. A nozzle intended to be set onto the skin is connected with the chamber of the pre-injection device and with the outlet of the main injection device by way of a kick-back valve. In addition, a pressure-production device that is connected with the chamber of the pre-injection device is configured to produce a high-pressure jet from the nozzle that penetrates the tissue. The chamber of the pre-injection device has a volume sized exclusively for producing an injection channel in the tissue, and the chamber of the main injection device has a volume intended for the medium to be injected.

In contrast, as disclosed in *Neracher* at page 9, lines 11-12, reference numeral 2 is the liquid contained in the capsule 3 for the administration under the skin of a human or animal patient, whereas reference number 7 refers to a compressible substance. Although in one preferred embodiment of *Neracher*, the compressible substance 7 is a liquid, both liquids are separated from each other. Contrary to the Examiner's position, liquid 2 in the capsule 3 is injected in *Neracher* and substance 7 is not injected. The compressible substance 7 under pressure is a

primary source of potential energy for propelling the liquid to be injected. See *Neracher* at page 9, lines 16-18. Thus, substance 7 is part of the propulsion system as well as the valves 14 and 15 in *Neracher*. These two valves are part of the propulsion-regeneration cycle of the compressable substance 7. See *Neracher* at page 11, line 30 to page 12, line 10. The injectable liquid 2 does not pass one of these valves.

Applicant also notes that reference number 206 of FIG. 2 of *Neracher* discloses an alternate embodiment of a pressure retaining means in the form of a releasable trigger mechanism. See *Neracher* page 13, lines 16-17.

As more specifically recited in Applicant's claim 3 as amended, the chamber of the main injection device has a piston that can be moved by hand. In contrast, with *Neracher* the piston 9 is used to compress the compressible substance 7 in which the displacement of the piston 9 is performed by a mechanism 8 which thread a ram portion 24 into the container. See *Neracher*

page 12 lines 23-27. The mechanism 8 is used to load the propulsion system which is a different step than the injection of the main injection volume as recited in Applicant's claim 3 as amended.

Claim 5 is dependent on claim 4, and more specifically recites that the pre-injection device has a coupling device for a connection with a main injection device that contains the medium to be injected. In contrast, reference number 237 of *Neracher* refers to a housing portion for the moveable stop pin 234. See *Neracher* page 13, lines 29-30. The moveable stop pin is part of the releasable trigger mechanism of the pressure retaining means 206. See *Neracher* page 13, lines 16-19. The alternative pressure retaining means cannot be used as a coupling device to connect a pre-injection device and a main injection device as recited in Applicant's claim 5 as amended.

Claim 6 as amended is dependent on claim 1, and more specifically recites that the pressure producing device of the pre-injection device of the pre-injection device has a pressure plate biased by a spring force, or a biased pressure piece. In contrast, *Neracher* discloses the use of a pressure retaining means 206, which contains a moveable stop pin 234 with a flange 239. The flange 239 is engaged by a spring. Further, the moveable stop pin 234 is pressed against the piston 210. See page 13, lines 29-31 of *Neracher*. This device is used to retain the potential energy, which is stored in the compressed substance 7, which can also be seen by the direction of the spring force, which is perpendicular to the direction of injection. In contrast, Applicant's device as recited in claim 6 as amended uses a spring as an energy source for the propulsive force.

Claim 7 more specifically recites that the pre-injection device has a channel connected with the nozzle at one end and the main injection device at the other end. Although the Examiner

has taken the position that a channel 205 is connected with the nozzle 20 of the pre-injection device of *Neracher*, it is respectfully submitted that the Examiner is incorrect. Although no explanation of the reference numeral 205 has been found in *Neracher*, it is believed that channel 205 is the housing of the pistol 210 as one can see at FIG. 2 of *Neracher*. It is respectfully submitted that if there were to exist a direct connection between the channel 205 and the nozzle 20 as suggested by the Examiner, the injection device of *Neracher* would not work.

As more specifically recited in claim 8, as amended, a kickback valve is disposed within the channel. The kickback valve 5 in channel 8 of Applicant's device is part of the injection system. The kickback valve 5 is needed for the successive injection of the pre-injective volume and the main injective volume. It is used to retain the main injective volume until the pre-injection has finished and closes the connection

between the two parts. *Neracher*, however, discloses the use of valves 14 and 15 as parts of the propulsion system.

As more specifically, recited in claims 9 and 10, as amended, a trigger of the pre-injection device holds a pressure plate biased by a spring or a pressure piece in its base position (claim 9) wherein the trigger is connected with the chamber of the pre-injection device and is configured to release the pressure plate above planned pressure (claim 10). In contrast, it is respectfully submitted that the first embodiment shown in FIG. 1a of *Neracher* does not use any spring. Further, the differences between the use of the spring in the pressure retaining means 206 and Applicant's device have already been discussed above with respect to amended claim 6 above.

Claim 11, as amended, more specifically recites that a membrane is part of the piston with which the chamber of the injection medium is connected, and that this membrane activates

the trigger by way of a pusher. In contrast, reference number 235 of *Neracher* refers to the abutment shoulder, which belongs to the moveable stop pin. *Neracher* discloses in the second embodiment an actuation lever 240 that is located under the flange 239 of the stop pin 234 as actuation system. The actuation lever is used to lift the pin and disengage it from the piston 210. See *Neracher* page 13, line 29 to page 14, line 2. Thus, *Neracher* uses a direct actuation system.

In contrast, Applicant's membrane 12 belongs to the indirect actuation system in which the user increases the pressure in the main injection system after the nozzle is placed on the patient's skin. The pressure is transferred to chamber 4 containing the pre-injection medium via channel 8. Thus, the membrane 12 is pressed against the pusher 13, which actuates the release of the spring force, if the appropriate pressure is reached.

As more specifically recited in claim 12, as amended, the channel has a connection with the chamber of the injection medium, and the kick-back valve is disposed between the connection and the coupling device. In contrast, container 4 of *Neracher* comprises the pressure generating and pressure retaining means. Two pistons 9 and 10 define two volume chambers 12 and 13, which are separated by a separating wall 11. The valves 14 and 15 are located in the separating wall as a connection of the two chambers. Before injection, the compressable substance 7 is mainly located in chamber 12. After the actuation valve 14 has opened, the compressable substance 7 flows in the front chamber 13. Thus, the propulsive force is transmitted to the piston 10, which is translocated to inject the injection liquid 2. After the injection has finished, the compressable substance is relocated into chamber 12 by moving the piston 9 backwards. See *Neracher* page 11, line 30 to page 12, line 10). A coupling device is used by Neracher to couple the capsule 3 with the propulsion system.

In contrast, with Applicant's device as recited in claim 12 as amended, channel 8 contains the pre-injection medium. Connection 3 is needed in order to allow filling and emptying of the chamber 4 via the channel 8. The kickback valve 5 is provided in channel 8 to avoid feedback from chamber 4 in order to ensure a safe injection. The coupling device 9 is needed to couple the pre-injection system with the main injection system.

As more specifically recited in Applicant's claim 13, as amended, the chamber has a piston that rests against the pressure plate and can be displaced in length, and the channel is guided through the piston and the pressure plate. In the propulsion system of *Neracher*, the pistons 9 and 10 do not rest against the separating wall 11 because chambers 12 and 13 contain the compressable substance 7. The pistons are constructed as one piece. See *Neracher* page 12, lines 3–7. No further pressure plate is located between the piston and the compressable substance 7. See FIG. 1a of *Neracher*.

In contrast, Applicant's propulsion system as recited in claim 13, as amended, is divided by channel 8 into two parts. The pressure plates are located between the springs, which produce the propulsive force, and the pistons. Pressure plates and pistons are translocated both during the injection whereas the spearating wall 11 is fixed in the *Neracher* system.

As recited in Applicant's claim 14 as amended, the main injection device and the pre-injection device have a common nozzle. As discussed above with respect to claim 2, the injection device disclosed by *Neracher* contains only one injection volume in one injection device and therefore only one nozzle exist.

As recited in Applicant's claim 15 as amended, a trigger of the pre-injection device can be indirectly activated by the pressure produced by the main injection device. In contrast, the actuation system disclosed by *Neracher* is actuated directly. The system is stored in the loaded state after the compression of the compressable substance 7 using the pressure retaining means 6 and 206, respectively. The injection is actuated, if the user presses the button 16. See *Neracher* page 12, line 10. The mechanism of the second embodiment is explained above with respect to

Applicant's claim 11. Further direct actuation systems are disclosed in FIGS. 3 to 5 of *Neracher*.

As recited in Applicant's claim 16 as amended, the pre-injection device and the main injection device have a common chamber for accommodating the medium to be injected, and a common pressure-production device. The pressure-production device has means for reducing the size of a first, slight part of the chamber in a first step, by a small volume, at a great pressure, and, in a second step, by a great volume, at a low pressure.

In contrast, as discussed above the injection device disclosed by *Neracher* does not contain a pre-injection device and a main injection device. Containers 4 and 204 contain the compressable substance 7, which is a primary source of potential energy. See *Neracher* page 9, lines 14 – 18. The volume, which contains the injectable liquid 2, is capsule 3 as discussed above with respect to Applicant's claim 2. Reference numeral 5 does not refer to a pressure production device, but rather to a pressure transmitting member in the form of a piston. See *Neracher* page 9, lines 14-15. Reference number 206 refers to the pressure retaining means of the second embodiment.

As more specifically recited in Applicant's claim 17 as amended, the common pressure-production device has a single spring and damping means for damping the movement of a piston that delimits the common chamber. With *Neracher's* arrangement, the potential energy for propelling the liquid to be injected is the compressable substance 7 under pressure. See page 9, lines 16–18 of *Neracher*. A spring is used only in the second embodiment as a part of the pressure retaining system as discussed above with respect to Applicant's claim 6. The piston 10 of the pressure transferring device 5 does not contain any spring in *Neracher*. Using the injection device disclosed by *Neracher*, it is possible to decrease the volume of the liquid to be injected by threading the ring 242 towards the stop 244. See page 14, lines 10–12 of *Neracher*. Thus, the complete volume to be injected can be regulated. Further, *Neracher* discloses the use of a second energy source to inject a second part of the injectable volume with a lower pressure. See page 14, line 14–page 15, line 7 of *Neracher*.

Accordingly, it is respectfully submitted that claims 1 and 4, as amended, and new claim 25, together with claims 2-3 and 6-20, claim 5, and claims 22-24, which depend directly or

indirectly on amended claim 1, amended claim 4, or new claim 25, are patentable over *Neracher*.

Dixon which has been cited against Applicant's claims 1, 13-14 and 17-18 likewise fails to anticipate Applicant's invention as recited in those claims. The injection device disclosed by *Dixon* contains two sections A and B. The front section A is the injector portion and the rear section B is the power pack assembly. See column 3, lines 30–33 of *Dixon*. Thus, only one volume loaded in the front part of section A is injected. Section B is used to generate the propulsive force which is needed to inject media needle in a needleness manner. There is no disclosure or suggestion of a device or method that uses a pre- and a main injection device for injecting two different media so that the pre-injection device can be used instead of a needle in combination with, for example, normal syringes.

With respect to Applicant's claims 13 and 14, these claims recite additional features that it is respectfully submitted are nowhere disclosed or suggested by *Dixon*. *Dixon's* device discloses a cylinder 44 which can be loaded with the medium to be injected. The piston 47 is located at one end of the cylinder. See column 4, lines 53-54 of *Dixon*. This piston is used for the loading procedure as well as for the injection. See column 4, lines 66-68 of *Dixon*. Thus, the piston 47 of *Dixon* is located inside the cylinder 44. Reference number 21 refers to a lock collar which is located inside the cup-shaped bushing 18. See column 3, line 54. This lock collar is part of the pressure retaining means of the propulsion system.

In contrast to *Dixon*, Applicant's device as recited in claim 13 and 14, as amended, uses a two-step injection system. Channel 8 is guided through the propulsion system and chamber 4 which contains the pro-injection medium. Thus, the propulsion system is located at both sides of channel 8. Channel 8 is used to

connect the nozzle, chamber 4 containing the pre-injection medium and the main injection device 17. Thus, with Applicant's device it is possible to use a needleless injection device in combination with a normal syringe in order to inject bigger volumes. The coupling of a main injection device like a syringe with a needleless injection device disclosed by *Dixon* is not possible because the propulsion system is located behind the piston which limits the injection chamber.

With Applicant's device as recited in amended claims 13 and 14, the pressure plate 7 is located between the piston 6 and the spring 14 in order to push the piston forward equally. Moreover, the injection device disclosed by *Dixon* contains only one volume to be injected in one injection device and thereby only one nozzle exists.

With respect to claims 17-18, it is respectfully submitted that the features recited in these claims are likewise nowhere disclosed or suggested by *Dixon*. *Dixon* discloses different

springs in order to inject the medium with different pressures. See claim 1 of *Dixon*. In contrast, with Applicant's device as recited in amended claims 17 and 18, the pre-injection medium is injected with a high pressure. This pressure is generated by the springs located in the propulsion system. After the injection of the pre-injection medium, the injection channel has been established. Then the main injection can be performed manually.

In summary, both *Neracher and Dixon* disclose needleless one step injection systems in which the injection can be performed using different pressures in order to regulate the injection depth and thereby different propulsion systems are used, however, using the devices in *Neracher and Dixon*, only one limited volume can be injected. In contrast, with Applicant's invention as recited in amended claims 1 and 4, and new claim 25, a two-step injection procedure can in fact be implemented. Due to the different nature of the assembly of Applicant's pre-injection device, in which a pre- and a main injection device are used, two different media can be injected, and thus, the pre-injection

device can be used instead of a needle in combination with, for example, normal syringes.

Accordingly, it is respectfully submitted that the claims are patentable over the cited references.

In summary, claims 1-20 and 22-24 have been amended, claim 21 has been canceled, and new claim 25 has been added. In view of the foregoing, it is respectfully requested that the claims be allowed and that this case be passed to issue.

Respectfully submitted,
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